

Enclosure

Additional Information for
an Amendment to NR-0122-D-101-B
Transmission Gauge, Change to the MK 1.0 Source Housing

Betacontrol of America application dated May 27, 2004, contained insufficient information on the issues below. Guidance on addressing the issues may be found in "Consolidated Guidance About Materials Licenses: Application for Sealed Source and Device Evaluation and Registration," NUREG-1556, Vol. 3, Rev. 1. The document is available at the NRC web-site: www.nrc.gov.

1. Description/Construction:

- 1.1 Please provide a summary of all differences, preferably in a table format, between the currently registered devices and the new designs that you wish to register.
- 1.2 Indicate how the new design will be distinguished from the old, e.g. the distribution of the new design will start with a specific serial number shown on the label.
- 1.3 Please confirm for the record that the units on the drawings are in millimeters.

2. Conditions of Use:

Confirm that the radionuclides and the maximum activity levels used by the MK 1.0 will remain the same.

3. Prototype Testing:

- 3.1 You have provided information regarding cycling of your device in normal operation. Please also provide information that the new housing for the MK 1.0, will maintain its integrity when subjected to likely accident conditions. In providing this information, you may use any of the methods listed in Section 10.5, Prototype Testing, NUREG-1556, Vol. 3, i.e., actual history of the product, engineering analysis, operational history, or comparison to similar or equivalent models. When referencing operational history in other countries please indicate how many units have been distributed, how long have they been in use, and failures if any, in normal use or accident conditions.
- 3.2 Provide the information regarding temperature, vibration, shock, and corrosion during the use, handling, storage, and transport of the device.

4. Radiation Profiles:

- 4.1 Provide the device type and the calibration date for the device used to measure the radiation profile of the new MK 1.0 source housing.
- 4.2 Provide a radiation profile, with the source in the shielded and unshielded positions, for the maximum activity for each of the radionuclides to be used, either measured or calculated.

5. Labels:

- 5.1 Provide a copy of the label that shows Betacontrol's address in the U.S.
- 5.2 The provisions of 10 CFR 32.51 for the distribution of generally licenses products have been changed since the latest amendment of your registration certificate. Please provide information on the label for your devices that is in compliance with the requirements of 10 CFR 32.51 (a)(3)(iii).

August 2, 2004

Mr. Markus Hannig,
Manager
Sales & Service
Betacontrol of America
P.O. Box 18
425 Route 202
Towaco, NJ 07082

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION ON AMENDMENT FOR
MK 1.0 TRANSMISSION GAUGE (NR-0122-D-101-B)

Dear Mr. Hannig,

This letter is in response to your application dated May 27, 2004, for an amendment to the registration certificate NR-0122-D-101-B to include a design change to the MK 1.0 transmission gauge source holder. In reviewing your application, we find that it is lacking required information. In the Enclosure of this letter, we have summarized the issues not addressed in your application.

Please submit the requested information within thirty days of the date of this letter. If we have not received complete information within thirty days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete application.

If you have any questions, please contact me at (301) 415-7138 or Dr. John P. Jankovich at 301-415-7904.

Sincerely,

/RA/

Tomas Herrera, Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

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